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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/676,032	09/29/2000	Joseph K. Agyin	6643R5	3249

30113 7590 08/27/2002

THE PROCTER AND GAMBLE COMPANY  
INTELLECTUAL PROPERTY DIVISION  
WINTON HILL TECHNICAL CENTER - BOX 161  
6110 CENTER HILL AVENUE  
CINCINNATI, OH 45224

EXAMINER

DELACROIX MUIRHEI, CYBILLE

ART UNIT PAPER NUMBER

1614

DATE MAILED: 08/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/676,032

Applicant(s)

AGYIN ET AL.

Examiner

Cybille Delacroix-Muirheid

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 29 January 2002 and 03 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4, 7-11, 13-15, 20 and 25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-11, 13-15, 20 and 25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

The following is responsive to Applicant's amendments, Terminal Disclaimer and remarks received Jan. 29, 2002 and June 3, 2002.

Claims 5, 6, 12, 16-19 and 21-24 are cancelled. No new claims are added.

Claims 1-4, 7-11, 13-15, 20, 25 are currently pending.

The previous objection to the specification set forth in paragraph 1 of the office action mailed Nov. 6, 2001 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

The previous claim objection set forth in paragraph 2 of the office action mailed Nov. 6, 2001 **is withdrawn** in view of Applicant's amendment and the remarks contained therein.

All previous claims rejections under 35 USC 102 and 35 USC 103(a) set forth in paragraphs 4-13 of the office action mailed Nov. 6, 2001 **are withdrawn** in view of Applicant's amendment and the supplemental remarks received Jan. 29, 2002 and June 3, 2002.

The previous double patenting rejection set forth at paragraphs 14-15 of the office action mailed Nov. 6, 2001 **is withdrawn** in view of the Terminal disclaimer received Jan. 29, 2002.

### ***New Ground(s) of Rejection***

#### ***Specification***

1. The disclosure is objected to because of the following informalities: The use of trademarks such as TAXOL, etc., have been noted in this application. Please see pages 17 and

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22. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Appropriate correction is required.

### ***Information Disclosure Statement***

The copending applications listed in the Information Disclosure Statement received Oct. 30, 2000 have been considered. The Examiner has lined through these citations because the copending application information will not be printed.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4, 7-11, 13-15, 20, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ram et al. (Already of record)

Ram et al. disclose a benzimidazole compound which reads on the claimed generic compound, i.e. compound #17 in Table 1 on page 541 wherein the benzyl is substituted with a Fluorine. This compound has pharmaceutical activity, i.e. antineoplastic activity.

Ram et al. do not disclose that the benzyl is unsubstituted as required by Applicant's claims. However, modification of the compound of Ram to substitute the fluorine with a hydrogen would have been obvious to one of ordinary skill in the art because, absent evidence to the

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contrary, such a substitution would not be expected to materially alter the anti-neoplastic activity of the compound. This is further evidenced by the fact that both Applicant's compound and the claimed compound have the same activity. Therefore, the Examiner respectfully submits that the claimed compound and the compound of Ram share close structural similarity and one of ordinary skill in the art would reasonably expect the two compounds to have similar antineoplastic activity.

Ram et al. do not specifically disclose pharmaceutical compositions or unit dosage forms comprising the disclosed compound; however, it would have been obvious to one of ordinary skill in the art to modify the compound of the prior art into a pharmaceutical composition or a unit dosage form because one of ordinary skill in the art would reasonably expect the compositions to be useful in treating cancer.

With respect to the specific pharmaceutical carriers and pharmaceutical forms or prodrugs, these are all art-recognized result-effective variables and it would have been obvious to one of ordinary skill in the art to modify them in the teachings of the prior art.

Concerning the claimed dosages, modification of dosage amounts is obvious and well within the capability of the skilled artisan.

Finally, concerning the pharmaceutical kit claim containing the instructions for use in treating cancer or viral infections (claim 25), modification of a composition into kit form is obvious and well within the capability of the skilled artisan. Moreover, the intended use of the composition

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embodied by the instructions is given no weight and fails to distinguish the claimed composition from the prior art.

***Conclusion***

Claims 1-4, 7-11, 13-15, 20, 25 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

CDM



Aug. 26, 2002



Cybille Delacroix-Muirheid  
Patent Examiner Group 1600